

**REMARKS**

The Official Action dated May 7, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claim 1 is amended to include limitations from claim 4, and claim 4 is cancelled. Claims 1, 5, 9, 14, 16, 19-22, 28, 30, 33 and 35 are amended for matters of form only. Claim 76 is added and contains limitations from claim 4. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 1-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Hoyng et al publication "Pharmacological Therapy for Glaucoma, A Review," *Drugs*, 59(3):411-434 (2000). The Examiner asserted that Hoyng et al teach the use of a combination of prostaglandins, beta-blockers and carbonic anhydrase inhibitors for the treatment of glaucoma and at page 426 teach the combination of timolol and latanoprost.

However, as will be set forth in detail below, Applicants submit that the methods defined by claims 1-37 are not anticipated by and are patentably distinguishable from Hoyng et al. Accordingly, this rejection is traversed, and reconsideration is respectfully requested.

More particularly, as defined by claim 1, the present invention is directed to a method of treating a patient suffering from severe glaucoma, exhibiting optical nerve head damage and visual field defects. The method comprises simultaneously administering a combination of IOP reducing agents to the patient's eye. As defined by claim 19, the invention is directed to a method of treating an individual in need of a high IOP-reduction. The method comprises simultaneously administering a combination of IOP reducing agents to the eye. Applicants

have surprisingly discovered that significantly higher intraocular pressure (IOP) reductions are obtained in patients or individuals suffering from severe glaucoma, i.e., exhibiting optical nerve head damage and visual field defects, and in patients or individuals having high IOP and therefore needing a high IOP reduction.

The Examiner's attention is directed to the present specification at pages 10 and 11, Tables 2.3 and 2.4. Table 2.3 shows results of methods according to the invention, namely treatment of individuals suffering from severe glaucoma, i.e., exhibiting optical nerve head damage and visual field defects, and in need of a high IOP reduction. Table 2.4 shows results of treatment methods for individuals who do not suffer from severe glaucoma and are not in need of high IOP reduction. A comparison of the results set forth in Tables 2.3 and 2.4 shows that significantly higher IOP reduction is obtained for the individuals of Table 2.3, thereby indicating better therapeutic effect in such methods employing simultaneous administration of a combination of IOP reducing agents to the eye.

Hoyng et al disclose that the medical treatment of glaucoma employs application of ocular hypotensive agents for reducing intraocular pressure (IOP). At page 426, the combination of timolol with latanoprost is disclosed. However, at page 415, Hoyng et al disclose that surgical intervention is typical for progressed glaucoma disease. Thus, in contrast to the methods of claim 1, directed to treatment of a patient with severe glaucoma, and the methods of claim 19, directed to treatment of individuals in need of high IOP reduction, Hoyng et al teach surgical procedures for treatment of such patients or individuals. In contrast, the present methods employ simultaneous administration of a combination of IOP reducing agents to the eye. Hoyng et al provide no teaching in this regard and, in fact, teach away from the present methods in disclosing that surgical intervention is appropriate.

Anticipation under 35 U.S.C. § 102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Hoyng et al to disclose methods for treating a patient suffering from severe glaucoma, exhibiting optical nerve head damage and visual field defects, as recited in claim 1, or methods of treating an individual in need of a high IOP-reduction, as recited in claim 19, by simultaneously administering a combination of IOP reducing agents to the eye, Hoyng et al do not describe, either expressly or inherently, each and every element as set forth in the present claims. Thus, Hoyng et al do not anticipate the present claims. It is therefore submitted that the rejection under 35 U.S.C. § 102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. §102, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By

  
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